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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/589,476	06/07/2000	Dennis A. Carson	103.021US1	1184

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EXAMINER	
KRASS, FREDERICK F	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/589,476	CARSON ET AL.	
	Examiner	Art Unit	
	Frederick F. Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,11,13,14,26-29,34 and 35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,11,13,14,26-29,34 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/9/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Obviousness Rejections

1) Claims 1, 3, 4, 13 and 34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Rephaeli (USP 5,939,455).

This rejection is maintained.

Applicant argues that the prior art is inapplicable because it "does not ascribe any therapeutic effect against the cancer cells to the NSAIDS – these are used to protect the active ingredient from degradation." (Remarks, p. 6, ¶ 1; emphasis original).

Applicant also urges reconsideration of the claims because they recite that the NSAID (e.g., etodolac) is administered in an amount that is *per se* effective to kill cancer cells, which is not disclosed or suggested by the prior art. (Remarks, p. 6, ¶ 2). Accordingly, Applicant concludes:

> Thus, in order for one of ordinary skill in the art to find the presently-claimed invention obvious in view of the full disclosure of the '455 patent, the art worker would be required to ignore the explicit teachings that the B-oxidation inhibitor, such as etodolac, including R(-) etodolac, functions to protect the active agent from degradation and use it as the active agent to inhibit multiple myeloma cells. It is respectfully submitted that there is no teaching in the '455 patent that would reasonably teach the art worker to believe that this should even be attempted, much less that it would be accomplished. Furthermore, there is even less in the cited document that would lead the art worker to believe that the B-oxidation inhibitor, such as etodolac, would itself maintain the viability of normal cells while killing the cancer cells, as recited in the instant claims. (Remarks, p. 6, last ¶; emphasis original).

The examiner disagrees. The instant claims employ the open transitional phrase "comprising" which permits the inclusion of additional active ingredients (such as the butyric acids of the prior art). Moreover and contrary to Applicant's arguments, protection of the additional active agent (the butyric acid compound) from degradation is

in fact a type of therapeutic effect (albeit an indirect one) since it increases the efficacy of the treatment method overall. Nothing in the instant claims requires that the NSAID act directly, as a sole active agent.

2) Claims 11, 14, 26-29 and 35 were rejected under 35 U.S.C. 103(a) as being unpatentable over Rephaeli (USP 5,939,455) in view of WO 98/09603.

This rejection is maintained with regard to claims 11, 14, 26-28 and 35.

It is withdrawn with regard to claim 29.

Applicant argues that the prior art is not applicable for the same reasons outlined in subsection "1)" supra. Furthermore, Applicant argues that the prior art does not provide any direction for selecting the particular NSAID concentrations and dosages used instantly, which are unexpectedly effective in killing cancer cells.

The examiner agrees with respect to instant claim 29, and has withdrawn the rejection of same over this combination of references. The examiner does not does not agree, however, with regard to the remaining claims. Applicant argues that the secondary reference working examples test R-flurbiprofen and thus the prior art

> [P]rovides no information regarding the dosing needed for any other NSAIDS to obtain an antiproliferative effect yet alone a killing effect. Because the '603 application claims any R-NSAID, one of ordinary skill in the art is left with potentially an unlimited number of dosing ranges to test to determine the anti-proliferative concentrations of a particular R-NSAID. (Remarks, passage bridging pps. 7 and 8).

The examiner does not see how the facts of record support this conclusion. The dosages used instantly (e.g., 1000-5000 mg/day as recited by instant claim 28) are in fact equally as broad as those suggested by the prior art (1-2000mg in single or divided

doses, as disclosed at the last line of p. 11 bridging to p. 12 of the '603 specification). Applicant has not shown criticality within those broad ranges, which would not necessarily correlate to a plasma level of 500-700 uM, for which unexpected results have in fact been demonstrated.

Obviousness-Type Double Patenting Rejection

1) Claims 1, 3, 4, 11, 13, 14, 26-29, 34 and 35 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting rejection as being unpatentable over claims 10, 13 and 15 of copending Application No. 09/634,207.

2) Claims 1, 3, 4, 11, 13, 14, 26-29, 34 and 35 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting rejection as being unpatentable over claims 16-20 of copending Application No. 09/634,207 in view of Spiegelman et al (USP 6,552,055).

Rejections "1)" and "2)" are maintained pending the terminal disclaimer promised by Applicant. (Remarks, p. 8, ¶ 4).

3) Claims 1, 3, 4, 11, 13, 14, 26-29, 34 and 35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being

unpatentable over claims 1-9 and 12-23 of copending Application No. 10/682,790 in view of Spiegelman et al (USP 6,552,055).

This rejection is maintained.

Applicant argues that this rejection should be withdrawn since it is improper "as argued in the previous section for rejections under 35 USC § 103(a)", such that there is no motivation for combining the '790 claims with the '055 patent teachings. (Remarks, p. 9). This argument is not understood, however; it is unclear what "previous" arguments Applicant is referring to, since the rationale for combining the '790 claims with the '055 patent teachings is quite different from the rationale used in the rejections over the '455 patent.

Action is Final

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614